UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE BRISTOL-MYERS SQUIBB CO. CVR SECURITIES LITIGATION	:	Case No. 1:21-cv-08255 (JMF) ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

John J. Clarke, Jr.
Jessica A. Masella
Steven M. Rosato
Jessica Park Wright
DLA PIPER LLP (US)
1251 Avenue of the Americas
New York, New York 10020
(212) 335-4500

Attorneys for Defendants
Bristol-Myers Squibb Company,
Giovanni Caforio, M.D., and
Samit Hirawat, M.D.

Dated: May 12, 2023

Table of Contents

Table of Authorities

Page(s)

Cases

Page(s)

Page(s)

Statutes, Regulations, and Rules

The remaining defendants, Bristol-Myers Squibb Company ("BMS"), Giovanni Caforio, M.D., and Samit Hirawat, M.D., respectfully submit this memorandum of law in support of their motion to dismiss the second amended complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

Plaintiffs assert claims on behalf of a putative class for alleged securities violations based on public statements concerning a series of contingent value rights ("CVRs") that were issued by BMS in its merger with Celgene Corporation. In a previous opinion, the Court dismissed most of plaintiffs' claims with prejudice. *In re Bristol-Myers Squibb Co. CVR Sec. Litig.*, ___ F. Supp. 3d ____, 2023 WL 2308151 (S.D.N.Y. Mar. 1, 2023) [ECF No. 110]. This motion concerns the second amended complaint, in which plaintiffs tried to "address the deficiencies" identified by the Court in the few claims they were permitted to replead. *Id.* at *10. They have not done so.

The second amended complaint repeats all of the claims and most of the allegations from plaintiffs' previous pleading. Plaintiffs explain in a footnote that they have taken this confusing approach "for potential appellate purposes." Compl. ¶ 54 n.7 [ECF No. 115]. Their counsel has confirmed that the only claims they intend to replead are those against BMS, Dr. Caforio, and Dr. Hirawat under sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder.[1] *See* Appendix 2 (correspondence). The modest amendments

[1] In response to questions from defendants' counsel, plaintiffs have confirmed (1) that the second amended complaint repleads solely for purposes of appeal the claims under the Securities Act of 1933, the claims under Exchange Act § 14(a), and the claims under Exchange Act § 20(a) to the extent based on alleged § 14(a) violations, and (2) that no claims that have not already been dismissed with prejudice are being asserted against defendants Peter J. Arduini, Charles Bancroft, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Karen M. Santiago, Vicki L. Sato, Gerald L. Storch, or Karen H. Vousden. *See* Appendix 2. The second amended complaint abandons any claim against David V. Elkins.

plaintiffs offer to those remaining claims fall far short of "nudg[ing] their claims across the line from conceivable to plausible[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

Plaintiffs allege that BMS, its chief executive officer Dr. Giovanni Caforio, and its chief medical officer Dr. Samit Hirawat made materially false or misleading statements in twenty disclosures between December 8, 2019 and November 16, 2020 that discussed BMS's applications for FDA approval of liso-cel and ide-cel – two of the "milestone" therapies for which FDA approval by contractual deadlines were conditions to payment on the CVRs. *See* Compl. ¶¶ 233-77 (challenged statements). The CVRs expired without payment when the FDA did not approve liso-cel by its contractual milestone date.

The Court previously dismissed plaintiffs' securities fraud claims because plaintiffs had not alleged facts sufficient to support the required "strong inference" of scienter. *Bristol-Myers Squibb Co.*, 2023 WL 2308151 at *3-7; *see* 15 U.S.C. § 78u-4(b)(2). The second amended complaint doubles-down on this pleading failure. Plaintiffs' "motive" allegations are largely unchanged from those the Court already found to be inadequate. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *4-5; *see* Compl. ¶¶ 206-16. Likewise, amendments to plaintiffs' allegations of "conscious misbehavior or recklessness" are cosmetic, at best, including more inadmissible "opinions" from an unidentified "expert" about what the defendants "should have known" about the FDA approval process, *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *6, and three new "confidential witnesses" who offer irrelevant generalities about corporate reporting and recollections of their holiday vacation schedules. *See* Compl. ¶¶ 165, 177, 194. Plaintiffs' allegations about "embarrassing, but not 'extreme' setbacks during an unprecedented pandemic" still do not add up to "fraud." *Bristol-Myers Squibb Co.*, 2023 WL 2308151 at *6.

Scienter is not the only reason the latest iteration of plaintiffs' pleading should be dismissed. Plaintiffs also have failed to plausibly allege that any challenged statement was false "*at the time it was made*." *Id.* at *3 (emphasis in original; citation omitted). The complaint does not allege any contemporaneous facts conflicting with – or even raising any question about – any of the statements plaintiffs portray as "fraudulent." Other allegations demonstrate the truth of many of the statements based on plaintiffs' own pleading. Nor can plaintiffs avoid application of the statutory safe harbor for the subset of those statements that concerned the prospects and timing for FDA approval of liso-cel in the midst of a global pandemic, which were "classically forward-looking." *Id.* at *8 (citation omitted). Plaintiffs' only response is the same one they offered before – that the statements were false because BMS allegedly never intended to make payments on the CVRs and "slow-rolled" the FDA application process to achieve that result. The Court already considered and rejected that unfounded accusation, and the second amended complaint has done nothing to strengthen it.

The second amended complaint also fails to plausibly allege loss causation. It does not identify any "corrective disclosure" allegedly revealing the supposed "fraud." Instead, plaintiffs allege the price of CVRs fell in response to indisputably truthful reports concerning the FDA approval process, including that the FDA did not act on the liso-cel application in time for the conditions to payment under the CVRs to be met. Without any plausible primary violation, plaintiffs' "controlling person" claim under section 20(a) of the Exchange Act also cannot survive.

Given plaintiffs' repeated failure to plausibly allege any claim under the securities laws, the second amended complaint should be dismissed in its entirety and with prejudice.

BACKGROUND[2]

A. The Parties

BMS is a global biopharmaceutical company whose mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. Compl. ¶ 63. The individual defendants are or were BMS officers or members of its board of directors. *Id.* ¶¶ 64-82. Plaintiffs allegedly purchased or otherwise acquired CVRs in the Celgene merger or in the open market. *Id.* ¶¶ 58-62.

B. The CVRs

BMS issued the CVRs on November 20, 2019 in connection with the closing of its merger with Celgene. Compl. ¶¶ 1, 25. Under the merger agreement, which the parties entered into as of January 2, 2019, BMS agreed to provide Celgene stockholders with consideration consisting of one share of BMS common stock, $50.00 in cash, and one CVR in exchange for each share of Celgene common stock. *Id.* ¶ 122.

The CVRs provided holders a contingent right to receive payment of $9 per CVR, but only if applications for three separate Celgene product candidates were approved by the FDA by contractual milestone dates: (i) liso-cel, a CAR-T therapy that is a treatment for large B-cell lymphoma, by December 31, 2020; (ii) ozanimod, a treatment for relapsing multiple sclerosis, also by December 31, 2020; and (iii) ide-cel, a CAR-T therapy for refractory multiple myeloma, by

[2] Well-pleaded factual allegations are assumed to be true solely for the purpose of this motion to dismiss. *Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016). "The Court may also 'consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff upon which it relied in bringing the suit.'" *Id.* (quoting *ATSI Commc'ns Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)); *see Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Cited exhibits ("Exh.") are attached to the accompanying Declaration of John J. Clarke, Jr. dated May 12, 2023 ("Clarke Decl.").

March 31, 2021. *Id.* ¶¶ 112, 114. "If even *one* Milestone Drug was approved *one day* late, the CVRs would expire worthless." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *1 (emphasis in original); *see* Compl. ¶¶ 1, 112; 222.

On February 22, 2019, BMS and Celgene filed a joint proxy statement / prospectus seeking approval from their respective stockholders for the proposed transaction. Compl. ¶ 122; *see* Exh. 1. The terms of the CVR Agreement were disclosed in the proxy statement, and the filing included BMS management's estimate of a 45% probability that all three of the applications would be approved by their contractual milestone dates. Compl. ¶¶ 25, 123-25, 222; *see* Exh. 1 (Proxy Stmt.) at 50, 68, 157. With full knowledge of "the CVR payout structure," BMS and Celgene stockholders approved the merger on April 12, 2019. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *5; Compl. ¶ 126. The closing occurred on November 20, 2019, which is when the CVR Agreement became effective and the CVRs were issued. Compl. ¶¶ 25, 167. Once issued, the CVRs traded on the New York Stock Exchange until the CVR Agreement terminated. *Id.* ¶¶ 56, 184.

C. The FDA Applications

Plaintiffs allege that BMS never intended to make payment on the CVRs or to use "diligent efforts" to obtain FDA approval of the applications by the contractual milestone dates. Instead, they contend that BMS intended, as early as February 2019 when the proxy statement was filed, to "slow-roll the FDA application process . . . so that it would miss at least one FDA milestone and avoid making the $9 CVR payment worth $6.4 billion." Compl. ¶ 223; *id.* ¶¶ 233-78. The central focus of this unfounded assertion is the biologics license application for FDA approval of liso-cel.

Liso-cel is a CAR-T therapy – a chimeric antigen receptor immunotherapy designed to train a patient's own T-cells to recognize and attack cancer cells. It is used to treat patients with

large B-cell lymphoma. Compl. ¶ 17. Early studies indicated liso-cel had better efficacy and safety than two earlier CAR-T therapies. *Id.* ¶ 87; *see id.* ¶ 85 (describing CAR-T therapies).

"Celgene submitted the initial portion of Liso-cel's BLA to the FDA before the Merger. On December 18, 2019, less than one month after the Merger, BMS submitted the final . . . portion of the BLA, titled 'Chemistry, Manufacturing, and Controls' ('CMC') to the FDA." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *2; *see* Compl. ¶¶ 127, 130-31. On February 13, 2020, the FDA accepted the liso-cel application and granted it "Priority Review." Compl. ¶ 134. This meant the FDA had a tighter deadline to act – "four months shorter than its typical review time" – under the Prescription Drug User Fee Act of 1992 ("PDUFA"). *Id.* ¶ 132. The FDA's "target approval date" under PDUFA original was set "as August, 17, 2020, about four-and-a-half months before the drug's December 31, 2020 Milestone Deadline." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *2; *see* Compl. ¶ 134.

On March 23, 2020, "shortly after the start of the COVID-19 pandemic," the FDA requested BMS to supplement its CMC submission with data addressing the safety and reliability of the production process for liso-cel. *Bristol-Myers Squibb*, 2023 WL 2308151, at *2; *see* Compl. ¶ 138. BMS responded on April 15, 2020. Compl. ¶ 138. Weeks later, the FDA informed BMS that it was deeming the response to be a "major amendment" to the liso-cel application, which "automatically triggered [a] three-month extension of the [PDUFA] date" until November 16, 2020; the FDA's extended statutory deadline was still "weeks *before* the December 31, 2020" milestone date for liso-cel. *Id.* ¶ 140 (emphasis added). BMS promptly disclosed this development in a press release issued on May 6, 2020. *Id.* ¶ 241.

But the FDA was unable to issue a decision on the liso-cel application by its own November 16, 2020 deadline. "[T]he FDA's inspections of the [second of] two manufacturing

facilities slated to produce Liso-cel were not completed until early December 2020, only weeks before the Liso-cel Milestone Deadline." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *2; Compl. ¶¶ 141, 145, 257, 261, 269, 277. In a press release issued on the November 16, 2020 PDUFA date, BMS reported that the FDA "was deferring action" on the liso-cel application because the FDA had been unable to conduct its inspection of a facility in Texas operated by a subsidiary of Lonza AG "due to travel restrictions related to the COVID-19 pandemic." Compl. ¶ 276.

Plaintiffs allege that BMS failed adequately to prepare the liso-cel manufacturing facilities for FDA inspection. *Id.* ¶¶ 141-66. But plaintiffs admit both inspections were completed by the FDA, and that BMS addressed the FDA's observations as a result of the inspections, *before* the December 31, 2020 milestone date. *Id.* ¶¶ 154, 166; *see Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *2.

The FDA did not issue a decision on the liso-cel application by December 31, 2020, the contractual milestone date. On January 1, 2021, BMS issued a press release reporting that the date had passed without an FDA decision and that the CVR Agreement therefore had terminated automatically in accordance with its terms. Compl. ¶ 184. Five weeks later, on February 5, 2021, the FDA approved liso-cel. *Id.* ¶¶ 53, 288. The other two product candidates that were included in the conditions to payment on the CVRs, ozanimod and ide-cel, both received FDA approval before their milestone dates. *Id.* ¶¶ 53, 130, 191. But "notwithstanding [those] timely approvals," the CVRs "expired worthless[]" because the FDA narrowly missed approving liso-cel in time. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *2; *see* Compl. ¶ 53.

D. Challenged Statements

The remaining claims assert that a series of disclosures made by BMS, Dr. Caforio, or Dr. Hirawat in periodic reports, press releases, earnings calls, and investor presentations between

December 8, 2019 and November 16, 2020 were materially false or misleading. *See* Compl. ¶¶ 233-77. Most of the statements were challenged in plaintiffs' previous complaint, which was dismissed in its entirety. The second amended complaint adds four challenged statements. *See id.* ¶¶ 235, 263-68. A table listing the challenged statements is attached as Appendix 1.

The challenged statements fall into three categories – updates about developments in the FDA approval process that plaintiffs do not contend were false, *e.g.*, *id.* ¶¶ 241, 245, 277; forward-looking statements about BMS's expectations for approval, *e.g.*, *id.* ¶ 256; and opinion statements about FDA applications, *e.g.*, *id.* ¶¶ 257, 273.

Plaintiffs do not allege that any of the challenged statements was factually inaccurate. Indeed, their own allegations demonstrate the truth of many of the statements. For example, plaintiffs allege Dr. Hirawat said in December 2019 that BMS expected to complete the filing of the liso-cel BLA before year-end, *id.* ¶¶ 233, 235, while elsewhere the complaint admits BMS did so, *id.* ¶ 237. Similarly, plaintiffs assert that congressional testimony by Dr. Caforio on September 30, 2020 was false in stating the FDA had accepted the applications for liso-cel and ide-cel during 2020 "and granted priority review for both," *id.* ¶ 267, but elsewhere they allege the same facts, *see id.* ¶ 134 (FDA accepted liso-cel application in Feb. 2020 and granted it priority review), ¶¶ 188-91 (recounting ide-cel application process resulting in FDA approval before its milestone date).

Instead, plaintiffs sweepingly allege that all of the challenged statements were false or misleading because they did not disclose BMS's secret intention to "slow-roll" the FDA approval "process for [l]iso-cel . . . so that they would miss at least one FDA milestone and avoid making the $9 CVR payment." *See* Compl. ¶¶ 223, 226, 229, 234, 278. The complaint includes allegations

from eleven "confidential witnesses" – eight who were included in the previous complaint and three new ones – but none offers facts that actually conflicted with any challenged statements at the time they were made or otherwise support plaintiffs' fraud theory. *See id.* ¶¶ 47, 139, 144, 158-62. The second amended complaint also continues to cite hindsight criticisms by an unnamed "FDA Biologics Expert" who has no apparent personal knowledge of relevant facts. *See, e.g.*, *id.* ¶¶ 4 & n.1, 133-35, 138-39, 146-66, 203-05.

Plaintiffs allege the market price for CVRs declined between May 6, 2020 and December 31, 2020 when BMS reported "various delays in the [FDA] approval process" for liso-cel and, when the liso-cel milestone date passed without an FDA approval decision, "the remaining artificial inflation dissipated." Compl. ¶¶ 296-301.

E. Relevant Procedural History and Plaintiffs' Remaining Claims.

Plaintiffs filed the consolidated amended complaint on February 23, 2022, after the Court appointed lead plaintiffs. ECF No. 94. That pleading asserted claims under sections 11 and 12(a)(2) of the Securities Act of 1933, sections 10(b) and 14(a) of the Securities Exchange Act of 1934, and "controlling person" claims under section 15 of the Securities Act and section 20(a) of the Exchange Act. ECF No. 95. In an opinion and order issued on March 1, 2023, the Court granted defendants' motion to dismiss the consolidated amended complaint in its entirety, dismissing with prejudice all claims under the Securities Act and under section 14(a) of the Exchange Act while dismissing with leave to replead the claim under section 10(b) of the Exchange Act and the related section 20(a) claim. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *10.

In the second amended complaint filed on April 14, 2023, plaintiffs assert claims against BMS, Dr. Caforio, and Dr. Hirawat under section 10(b) of the Exchange Act and Rule 10b-5.

Compl. ¶¶ 64-66. They also assert "controlling person" claims against the two remaining individual defendants under section 20(a) of the Exchange Act. *Id.* ¶¶ 326-32.

LEGAL STANDARDS

To avoid dismissal under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). A facially plausible claim is one that enables the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The plaintiff "must allege facts showing 'more than a sheer possibility that a defendant has acted unlawfully.'" *In re Nielsen Holdings PLC Sec. Litig.*, 510 F. Supp. 3d 217, 224-25 (S.D.N.Y. 2021) (Furman, J.) (quoting *Iqbal*, 556 U.S. at 678). "If [p]laintiffs have not 'nudged their claims across the line from conceivable to plausible, [those claims] must be dismissed.'" *Schaffer v. Horizon Pharma PLC*, 2018 WL 481883, at *2 (S.D.N.Y. Jan. 18, 2018) (Furman, J.) (quoting *Twombly*, 550 U.S. at 570).

A plaintiff asserting a claim for securities fraud under section 10(b) and Rule 10b-5 must allege "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011). In addition to specifying allegedly fraudulent statements and the reasons they were false or misleading, 15 U.S.C. § 78u-4(b)(1), a securities fraud complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," that is, scienter. 15 U.S.C. § 78u-4(b)(2); *ATSI Commc'ns Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). The inference of scienter "must be more than merely plausible or reasonable – it must be cogent and at least as compelling

as any opposing inference of nonfraudulent intent." *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007); *see Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *6.

ARGUMENT

I. PLAINTIFFS' CLAIM FOR SECURITIES FRAUD SHOULD BE DISMISSED.

In the second amended complaint, plaintiffs have not cured the pleading deficiencies this Court previously identified in their claim under section 10(b) of the Exchange Act and Rule 10b-5. Plaintiffs have not plausibly alleged that any of the challenged statements – concerning the applications for FDA approval of liso-cel and ide-cel in the midst of the COVID-19 pandemic – was false or misleading when made. *See* Compl. ¶¶ 233-77. The second amended complaint also still fails to allege facts that would support the necessary strong inference of scienter, nor have plaintiffs pleaded loss causation.

A. Plaintiffs Have Not Plausibly Alleged a Material Misrepresentation.

1. Challenged Updates on the FDA Approval Process Were Accurate.

In the second amended complaint, plaintiffs still have not plausibly alleged that periodic updates provided from December 2019 through November 2020 by BMS and the individual defendants about the liso-cel and ide-cel applications were in any way false based on information available "at the time [the statements were] made." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *3 (citing *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014); *see* Compl. ¶¶ 233, 235, 237, 239, 242, 245, 247, 251, 252, 254, 256, 257, 259, 261, 263, 265, 267, 269, 270, 273, 274, 277 (Statements 1-7, 9-20); *see* 15 U.S.C § 78u-4(b)(1) (requiring plaintiff to specify statement and the reasons it was false).[3]

[3] The Court has dismissed with prejudice any claims based on statements that predate the alleged class period, which include disclosures contained in the joint proxy statement dated February 22, 2019 and statements in a Guggenheim Partners analyst report dated November 7, 2019. Compl. ¶¶ 220-231; *see Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *10. To the extent

As with their previous pleading, plaintiffs' second amended complaint does not even attempt to allege contemporaneous facts in conflict with these statements. They do not allege, for example, (i) that BMS did *not* complete its liso-cel BLA on December 18, 2019 (*i.e.*, "before the end of" 2019), Compl. ¶¶ 233, 235, 237 (Statements 1-3); (ii) that BMS did *not* "continue to advance [its] regulatory filings," *id.* ¶ 239 (Statement 4); (iii) that the FDA's "major amendment" letter had *not* extended the liso-cel PDUFA date, *id.* ¶ 245 (Statement 6); (iv) that the FDA had *not* asked "specific questions" about the liso-cel application, *id.* ¶ 251 (Statement 9); (v) that the extended PDUFA date for liso-cel was *not* November 16, 2020 after the FDA's "major amendment" letter, *id.* ¶¶ 239, 247, 251-52, 254, 256-57, 263 (Statements 6, 7, 9-12, 15); (vi) that the COVID-19 pandemic *would not* potentially "delay the timing of the FDA's approval decisions" or its inspection of manufacturing facilities, *id.* ¶¶ 245, 254, 257, 261, 270 (Statements 6, 10, 12, 14, 18); (vii) that BMS was *not* "committed to working with the FDA," or was *not* "working very actively with the FDA to keep the review and inspection process moving, *id.* ¶¶ 242, 257, 261, (Statements 5, 12, 14); or (viii) by the time Dr. Caforio testified to Congress at the end of September 2020, that the FDA had *not* accepted the liso-cel and ide-cel applications and granted them "priority review," *id.* ¶ 267 (Statement 17).

Rather than attempting to plead falsity with specific allegations, plaintiffs rely on their sweeping contention that all of the statements were false or misleading because BMS secretly planned to "slow-roll the FDA application process" in order to "avoid making the $6.4 billion CVR payment." Compl. ¶¶ 234, 236, 238, 240, 243, 246, 248, 250, 253, 255, 256, 258, 260, 262, 264, 266, 268, 271, 275, 278. But the second amended complaint still does not allege facts that

---

plaintiffs intend to reassert securities fraud claims against the remaining defendants based on those statements, they do not plausibly allege a securities violation for the same reasons and for the reason set forth in support of all defendants' previous motion to dismiss.

would support that assertion. Nor is there any plausible factual allegation to support plaintiffs' contention that "BMS knew," but failed to disclose, that its applications for FDA approval of liso-cel and ide-cel were "deficient," "insufficient," or "deliberately or recklessly incomplete." *See id.*

Plaintiffs' allegations that there were setbacks in the FDA approval process *after* the defendants made challenged statements are not sufficient: the securities laws did not require BMS or the individual defendants to predict the future. *See Gallagher v. Abbott Labs.*, 269 F.3d 806, 810 (7th Cir. 2001) ("Unless Abbott had a time machine, it could not have described on March 9 a letter that had yet to be written."). Truth or falsity instead must be "assessed in light of the information available at the time." *Scott v. Gen. Motors Co.*, 46 F. Supp. 3d 387, 394 (S.D.N.Y. 2014), *aff'd*, 605 F. App'x 52 (2d Cir. 2015); *see Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *3; *Panther Partners, Inc. v. Ikanos Commc'ns, Inc.*, 538 F. Supp. 2d 662, 673 (S.D.N.Y. 2008) (rejecting "'backwards' pleading – an attempt to allege liability for disclosures not made because the material fact was unknowable or had not even occurred"), *aff'd in relevant part*, 347 F. App'x 617 (2d Cir. 2009).

Similarly, hindsight opinions offered by plaintiffs' unnamed "FDA Biologics Expert" are not factual allegations and are not entitled to "a presumption of truthfulness." *In re NYSE Specialists Sec. Litig.*, 503 F.3d 89, 95 (2d Cir. 2007); *see Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199, 223-24 (S.D.N.Y. 2018) (refusing to consider opinions of food safety expert); *e.g.*, Compl. ¶¶ 195-96 (opining that pandemic cannot explain failure to obtain FDA approval by milestone date); *id.* ¶¶ 203-205 (opining that there is "statistically significant difference" in timelines for liso-cel and other FDA applications).

The second amended complaint also offers no factual allegations in support of its conclusory assertion that BMS was "deliberately or recklessly not preparing adequately for

inspections of its two [l]iso-cel manufacturing facilities." Compl. ¶¶ 246, 248, 250, 253, 255, 256, 258, 260, 262, 264, 266. For this, plaintiffs rely primarily on FDA comments issued *after* the inspections, *see id.* ¶¶ 145-49, 154-63, but that is just another example of impermissible hindsight pleading. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994); *Gissin v. Endres*, 739 F. Supp. 2d 488, 502 (S.D.N.Y. 2010). After-the-fact observations do not support an inference that BMS knew, months earlier, that those issues would be raised when the inspections occurred in the future. Compl. ¶¶ 151, 154.

Allegations from alleged "confidential witnesses" who worked for Lonza, not for BMS, also do not support a plausible inference that BMS or the other defendants were aware of any material issues at the time of the challenged statements. *Id.* ¶¶ 158, 160-65; *see Campo v. Sears Holdings Corp.*, 371 F. App'x 212, 217 (2d Cir. 2010) (dismissing claims where confidential witnesses did not know if defendants "actually accessed or reviewed the reports"); *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 594 (S.D.N.Y. 2011) (rejecting confidential witness allegations where complaint did not allege they "ever had any contact with anyone at [the company], much less with the Individual Defendants"). If anything, the information allegedly gleaned from those "confidential witnesses" shows that BMS was working diligently to ensure that the FDA approval process could be completed in time to meet the CVR milestone dates – directly contrary to plaintiffs' central allegation. *See* Compl. ¶ 158 (alleging BMS conducted mock audit, organized task force, and held regular calls with Lonza, and that a BMS employee "berated" CW #2 and complained about "how much money Bristol was spending at Lonza" when things "were not going well").

As a general matter, sponsors of FDA applications have no duty under the securities laws to provide details about facilities inspections. *See Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d

Cir. 1995) (rejecting claim based on alleged failure to disclose preliminary inspection results where "no materially adverse action was taken by the FDA," and company "had made commitments to the FDA to correct the plant deficiencies"); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 541-42 (S.D.N.Y. 2015) (no duty even to discuss *results* of FDA inspections) (collecting cases), *aff'd*, 816 F.3d 199 (2d Cir. 2016).

Nor did BMS assume a duty to discuss the *preparedness* for inspections of the two liso-cel manufacturing facilities when it commented on the effects of the COVID-19 pandemic on *scheduling* them given FDA imposed travel-restrictions. *E.g.*, Compl. ¶ 254 ("It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed."); ¶ 257 ("we are aware that some of the . . . same people who are at the FDA who [are working] on liso-cel, will also be pulled into the inspection related activities that might be coming along for the COVID-related vaccines"); ¶ 261 ("there's the COVID and the complexity of travel during this time and I would say that . . . somewhat increases the risk to the process"); ¶ 270 ("It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections . . ."); *see FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1305 (11th Cir. 2011) ("'Requiring that disclosures be 'complete and accurate' . . . does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise.'") (citation omitted).

2. The PSLRA Safe Harbor Bars Liability for Many Statements.

A number of the challenged statements also are protected from liability by the PSLRA safe harbor, which applies to any forward-looking statement made without "actual knowledge that it was false or misleading," that is "accompanied by meaningful cautionary language," or that is immaterial. 15 U.S.C. § 78u-5(c)(1)-(2); *see Slayton v. Am. Express Co.*, 604 F.3d 758, 766

(2d Cir. 2010). The challenged forward-looking statements include predictions about BMS's ability to meet the CVR milestones, Compl. ¶¶ 242, 277 (Statements 5, 20); discussion of potential delays in the approval process due to FDA travel restrictions due to the pandemic, *id.* ¶¶ 245, 254, 257, 261, 269-70 (Statements 6, 10, 12, 14, 18); and potential timing for filings or FDA approval of the applications, *id.* ¶¶ 233, 235, 249, 251, 256, 265, 274 (Statements 1, 2, 8, 9, 11, 16, 19).

All of those statements concern an ongoing FDA approval process, and "courts in this District have consistently held that 'statements about FDA approval . . . are 'classically forward-looking' because 'they address what defendants expect to occur in the future.'" *Bristol-Myers Squibb Co.*, 2023 WL 23018151, at *8 (quoting *Sanofi*, 87 F. Supp. 3d at 535).

Plaintiffs have not alleged facts that would support an inference that any of the defendants had "actual knowledge" of the falsity of any of these statements at the time they were made, for reasons already discussed and as addressed below. *See supra* at 12-15; *infra* at 18-22; 15 U.S.C. §§ 78u-5(c)(1). As with their claims generally, plaintiffs have not identified any "specific, *contemporaneous* reports or statements showing [d]efendants did not believe [statements] when they were made." *Nielsen Holdings*, 510 F. Supp. 3d at 231.

The statements also were accompanied by meaningful cautionary language. BMS provided CVR-specific risk factors in its Form 10-K, filed on February 24, 2020, and in its Forms 10-Q filed on May 7, August 6, and November 5, 2020. *See* Exhs. 2, 7, 10, & 13. In the Form 10-K, BMS identified as forward-looking any statement concerning, "among other things, . . . product development, product approvals, . . . [and] our ability to realize the projected benefits of the acquisition of Celgene[.]" Exh. 2 at 56. The risk factors warned that "if the milestones specified

in the CVR agreement are not achieved ***for any reason*** . . . , no payment will be made under the CVRs and the CVRs will expire without value." *Id.* at 27 (emphasis added).[4]

These warnings were reiterated in the Forms 10-Q. *See* Exh. 7 at 44; Exh. 10 at 51; Exh. 13 at 54. But in addition, the Forms 10-Q added a warning "that the COVID-19 pandemic could delay the timing of the FDA's approval decisions" and, if FDA review extended past the milestone dates, "no payment will be made under the CVRs and the CVRs will expire without value." Exh. 7 at 46; Exh. 10 at 53; Exh. 13 at 56. BMS referred investors to these cautionary statements in each of the press releases and earnings calls that plaintiffs challenge. *See* Exhs. 3-6, 8-9, 11-12, 14-15. The cautionary statements meaningfully warned investors about the risk that the CVRs might expire valueless if the FDA did not, for any reason, approve any of the three applications by its milestone date, which protects the speakers from liability. *See Bristol-Myers Squibb Co.*, 2023 WL 2301851, at *9; *Sanofi*, 87 F. Supp. 3d at 536.

3. Some Statements Were Inactionable Opinions or Expressions of Optimism.

Several statements are challenged for stating that BMS was "committed" to working with the FDA or obtaining FDA approval of liso-cel, that it would "continue to work closely" with the FDA, that it was "looking forward" to obtaining FDA approval, or that the regulatory process was "going well" and was "on track." Compl. ¶¶ 242, 247, 256-57, 261, 265, 274, 277 (Statements 5, 7, 11-12, 14, 16, 19, 20). These indefinite expressions of optimism and aspiration are not actionable. *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 174 (2d Cir. 2020); *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 183 (2d. Cir. 2014).

[4] The Court may examine the alleged misrepresentations and any accompanying cautionary statement in deciding this motion. 15 U.S.C. § 78u-5(e).

The statements also were opinions, and plaintiffs have not pleaded facts required to make them actionable after *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015). In *Omnicare*, the Court held that statements of opinion or belief cannot give rise to securities liability unless "either 'the speaker did not hold the belief she professed' or 'the supporting fact[s] she supplied were untrue.'" *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare*, 575 U.S. at 186). A complaint challenging opinion statements therefore must include allegations supporting a plausible inference that the speaker did not believe them or that they did not "fairly align[]" with information available *at the time*. *Id.* at 212 (quoting *Omnicare*, 575 U.S. at 189). Plaintiffs plead no such allegations. Instead they assert, "with the benefit of hindsight," that the "opinions turned out to be incorrect[.]" *Finger v. Pearson PLC*, 2019 WL 10632904, at *13 (S.D.N.Y. Sept. 16, 2019). That is not securities fraud.

B. Plaintiffs Do Not Allege Facts Supporting a "Strong Inference" of Scienter.

In its dismissal decision, the Court examined plaintiffs' failure to adequately allege scienter in the previous iteration of the complaint and found those allegations lacking. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *3-7. The second amended complaint adds cosmetic amendments to those allegations but still fails to plead facts supporting an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314; *ECA, Loc. 134 IBEW Jt. Pension Tr. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009), *see* 15 U.S.C. §§ 78u-4(b)(1)-(2).

1. Plaintiffs Rely on Previously Rejected Motive Allegations.

Plaintiffs previously alleged that the individual defendants were financially motivated to commit securities fraud because of their long-term incentive compensation packages and by an alleged desire to increase the value of BMS stock. *See* ECF No. 95, ¶¶ 143-52. But as the Court recognized in dismissing the last iteration of these claims, "the compensation packages at issue

were announced *months* after the Merger and after the CVRs were issued[,]" and plaintiffs' allegations about a desire to improve BMS's stock price constituted a "paradigmatic objective 'generally possessed by most corporate directors and insiders' and thus does not suffice." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *4 (quoting *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009)) (emphasis in original).

Despite those rulings, the second amended complaint relies on substantially the same allegations. *See* Compl. ¶¶ 206-16. There are no allegations of "insider trading" by either of the individual defendants, or anyone else. Plaintiffs have added only one new "motive" theory – that Dr. Caforio and other executives were "desperate to improve the Company's profitability at the time of the Merger[,]" and "[b]y avoiding the $6.4 billion payout in 2021, Caforio and the other Individual Defendants increased Bristol's net earnings in 2021 from $600 million to $7.0 billion." *Id.* ¶ 206. But that is the same kind of "paradigmatic objective" any corporate officer would have to make the corporation profitable, and it does not support an inference of scienter. *Bristol-Myers Squibb Co,*, 2023 WL 2308151, at *4; *see, e.g.*, *Gluck v. Hecla Mining Co.*, ___ F. Supp. 3d ____, 2023 WL 2161958, at *9 (S.D.N.Y. Feb. 22, 2023) ("Plaintiffs have put forth no cogent basis for Defendants to commit fraud other than the normal profit-making incentives of any corporate officer[.]"). It is little different from the already rejected allegation that the defendants were motivated to avoid paying $6.4 billion on the CVRs because that was nearly as much "as the Company's entire $7.0 billion in net earnings in 2021[.]" Compl. ¶ 214; ECF No. 95, ¶ 150.[5]

[5] The second amended complaint also repeats allegations concerning "the 'massive' size of the alleged fraud," despite the Court's express rejection of that allegation. *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *4. The added allegation that the $6.4 billion payment was "highly material" does not alter that conclusion. *See* Compl. ¶ 7. Other rejected scienter allegations also are repeated, including that intent can be inferred from BMS's decision not to buy back CVRs, *id.* ¶¶ 128-29, and that the CVRs' "three milestone 'all or nothing'" structure was "unusual, *id.* ¶ 173; *see Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *5. These rulings are the law of this case.

Plaintiffs' central allegation that the defendants were motivated to breach BMS's obligations under the CVR Agreement in order to avoid the $6.4 billion payment also "defies economic reason." *JP Morgan Chase Co.*, 553 F.3d at 203.[6] Any deliberate effort to prevent timely FDA approval undoubtedly would have exposed BMS to potential liability for breach of the CVR Agreement and therefore would not have "spare[d] [BMS] a $6.4 billion payout," as plaintiffs allege. *Id.* ¶ 7; *see In re AT&T/DirecTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 533 n.26 (S.D.N.Y. 2020) (rejecting allegation that AT&T "knew from the beginning" that product would be unprofitable because it would make "no economic sense" for AT&T to have made substantial effort to complete merger and invest in product "if it did not genuinely believe that" it would be "successful and profitable").

2. Plaintiffs Also Still Fail to Plead Conscious Misbehavior or Recklessness.

Because "there is no evidence of motive, . . . the strength of circumstantial allegations" of conscious misbehavior or recklessness "must be correspondingly greater." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *5; *see JP Morgan Chase Co.*, 553 F.3d at 198-99. As with the plaintiffs' previous pleading, the second amended complaint does not meet this "demanding requirement[.]" *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *5.

Plaintiffs continue to premise their arguments about "conscious misbehavior or recklessness" on BMS "having allegedly made ten missteps during the [l]iso-cel approval process." *Id.* Based on allegations from their unidentified FDA "expert," plaintiffs characterize those "missteps" as "rare," "unusual," or "contrary to standard industry practice."

[6] Indeed, many individuals working to obtain timely approval for the liso-cel and ide-cel applications were former Celgene employees who received CVRs in the merger and whose interests therefore aligned with other CVR holders in seeking timely FDA approval. *See* Exh. 1 at 203-04 (describing treatment of Celgene equity awards in merger).

Compl. ¶¶ 283-89; *see also id.* ¶¶ 153-54, 166. As the Court previously observed, even if this were not just a claim of inactionable "mismanagement," plaintiffs have not alleged that any individual defendant had knowledge of those purported "missteps." *Bristol-Myers Squibb Co.*, 2023 WL 23018151, at *5.

In an attempt to respond to this pleading deficiency, plaintiffs have added some generalized allegations concerning the management or board responsibilities of the individual defendants. *See* Compl. ¶¶ 173-82. But none of those allegations shed any light on what either Dr. Caforio or Dr. Hirawat actually knew, or when they knew it, about any specific "misstep" that purportedly "delayed the [l]iso-cel approval until just after the CVR deadline." *Id.* ¶ 176. Nor are there any allegations to suggest knowledge of any such facts that conflicted with challenged disclosures at the time they were made.

Allegations rooted in speculation from new confidential witnesses are equally unavailing. CW #9, who is alleged to have been "part of a team that contributed updates to senior management in 2020," allegedly told plaintiffs that Dr. Caforio and other senior officers "would have been aware of" issues with the liso-cel application, such as the "major amendment delay" and the Form 483s from the FDA. *Id.* ¶ 177. CW #10 added that, as chief executive officer, Dr. Caforio "should have been apprised" of these developments. *Id.* ¶ 172 n.11.[7]

But the complaint itself alleges that BMS disclosed developments with the relevant applications as they occurred. *See, e.g.*, *id.* ¶¶ 241, 245, 247, 251, 257, 269, 273, 274, 276. Despite having more than two years to investigate, there still is not a single allegation, from the "confidential witnesses" or otherwise, that any defendant actually knew facts about the FDA

[7] CW #11 allegedly told plaintiffs' counsel their request was granted to take vacation in mid-December 2020 notwithstanding the upcoming liso-cel milestone date. Compl. ¶ 165. This alleged employee's vacation schedule does not shed any light on any defendant's state of mind.

approval process that conflicted with their challenged statements at the time they made them. *See Bristol-Myers Squibb*, 2023 WL 2308151, at *6 (noting that none of plaintiffs' confidential witnesses were "alleged to have ever interacted with any Executive Defendant regarding liso-cel"); *Glaser*, 772 F. Supp. 2d at 594 (rejecting general allegations of CWs "concerning the corporate environment" as "insufficient to support scienter").

Similarly, just as before, hindsight *opinions* of plaintiffs' unidentified "FDA Biologics Expert" shed no light on scienter. Views of purported experts are not probative of, or even relevant to, "the state of mind or knowledge of a party." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *6 (collecting cases). In addition to repeating plaintiffs' prior "expert" allegations, *see, e.g.*, Compl. ¶¶ 29, 49, the second amended complaint adds allegations in which their "expert" downplays the impact of the COVID-19 pandemic by comparison with other FDA applications. *See id.* ¶¶ 52, 195-96, 203-05 (opinion that liso-cel approval timeline was "statistically anomalous"). That type of "empirical and statistical analysis" is not a basis to infer scienter for the defendants in this case, who in the challenged statements only were discussing facts related to the relevant BMS applications at the time. *See In re Hansen Natural Corp. Sec. Litig.*, 527 F. Supp. 2d 1142, 1155-56 (C.D. Cal. 2007).

As with plaintiffs' previous complaint, "the more compelling inference to be drawn from the pleaded facts is that both BMS and the FDA experienced embarrassing, but not extreme setbacks during an unprecedented pandemic." *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *6 (internal quotations omitted). In its most charitable reading (and one that the defendants reject), plaintiffs have alleged no more than "corporate (or government agency) mismanagement, which does not, by itself, give rise to a strong inference of scienter." *Id.*

C. Plaintiffs Have Not Plausibly Alleged Loss Causation.

Plaintiffs also have not plausibly alleged a "causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005); *see* 15 U.S.C. § 78u-4(b)(4) (loss causation is plaintiffs' burden). Meeting that burden requires plausible allegations of a "corrective disclosure." *Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 494 (S.D.N.Y. 2021). Where such a disclosure "contain[s] no information that even remotely suggests that [d]efendants' prior statements . . . were false or misleading[,]" dismissal is required. *Id.* (citing *Lentell*, 396 F.3d at 175 n.4).

None of the alleged "corrective disclosures" here revealed a "fraud" that had been concealed by a previous misrepresentation. While the price of CVRs allegedly declined after disclosures on May 6, September 8, November 5, and November 16, 2020, Compl. ¶¶ 297-300, there are no facts alleged that would permit an inference that the price declines were in response to the revelation of fraud. Instead, the plausible inference is that the price responded to an increased risk that a CVR milestone would be missed resulting in no payment, which was precisely the risk BMS repeatedly consistently warned could materialize. *Id.* ¶¶ 245, 254, 270.

"There is no allegation that the market reacted negatively to a corrective disclosure *regarding the falsity*" of any prior statement, "and no allegation that [BMS] misstated or omitted risks that did lead to the loss." *Lentell*, 396 F.3d at 175 (emphasis added). Plaintiffs instead rely on accurate updates concerning the FDA approval process "and concomitant market dissatisfaction to allege loss causation. That is simply not enough." *Born*, 521 F. Supp. 3d at 494.

II. PLAINTIFFS' "CONTROLLING PERSON" CLAIM ALSO SHOULD BE DISMISSED.

A "controlling person" claim under section 20(a) of the Exchange Act requires "a primary violation" and control of the primary violator by defendants. *JP Morgan Chase Co.*,

553 F.3d at 206-07. Plaintiffs' failure to allege a primary violation of section 10(b) of the Exchange Act alone requires dismissal of their section 20(a) claim. *Id.*; *Bristol-Myers Squibb Co.*, 2023 WL 2308151, at *9.

The claim also should be dismissed because plaintiffs have not alleged that any controlling person "was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI*, 493 F.3d at 108. Plaintiffs have not adequately alleged that either Dr. Caforio or Dr. Hirawat was a culpable participant in any violation of section 10(b). *ATSI*, 493 F.3d at 108. That would require "a showing of both fraudulent conduct and a culpable state of mind." *E.g.*, *In re Weight Watchers Int'l Inc. Sec. Litig.*, 504 F. Supp. 3d 224, 264 (S.D.N.Y. 2020); *see ATSI*, 493 F.3d at 108. The complaint lacks any "particularized facts" to support such a conclusion as to either Dr. Caforio or Dr. Hirawat. *Weight Watchers*, 504 F. Supp. 3d at 264.

III. THE COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE.

The Court's opinion and order put plaintiffs "on notice of deficiencies in" the consolidated amended complaint and granted plaintiffs an opportunity to cure those deficiencies. *Dietrich v. Bauer*, 76 F. Supp. 2d 312, 351 (S.D.N.Y. 1999). Where, as here, the plaintiffs already have been given an opportunity to amend their complaint and have failed to cure the defects in it, "[n]o additional opportunity is warranted[,]" and the complaint should be dismissed with prejudice. *In re Hebron Tech. Co. Sec. Litig.*, 2021 WL 4341500, at *25 (S.D.N.Y. Sept. 22, 2021).

CONCLUSION

For the foregoing reasons, the second amended complaint should be dismissed in its entirety and with prejudice.

Dated: New York, New York
May 12, 2023

DLA PIPER LLP (US)

By: /s/ John J. Clarke, Jr.

John J. Clarke, Jr.
john.clarke@us.dlapiper.com

Jessica A. Masella
jessica.masella@us.dlapiper.com
Steven M. Rosato
steven.rosato@us.dlapiper.com
Jessica Park Wright
jessica.wright@us.dlapiper.com
1251 Avenue of the Americas
New York, New York 10020
Tel: (212) 335-4500

Attorneys for Defendants
Bristol-Myers Squibb Co.,
Giovanni Caforio, M.D., and
Samit Hirawat, M.D.

APPENDIX 1

In re Bristol-Myers Squibb Co. CVR Securities Litigation, Case No. 1:21-cv-08255 (JMF)
Chart of Allegedly False or Misleading Statements[1]

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
1	¶ 233	12/8/19	Source: Presentation at American Society of Hematology Alleged Speaker: Samit Hirawat	"On December 8, 2019, [Dr. Samit] Hirawat presented at the American Society of Hematology conference. According to a subsequent analyst report, he 'reiterated plans to file liso-cel for approval by the end of the year, which the report noted 'should ease concerns on timing for the CVR.'"	• Statement not adequately alleged to be false or misleading • Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable statement of opinion under *Omnicare* • Statements not attributable to BMS or any individual defendants • No scienter
2	¶ 235	12/9/19	Source: Investor Webcast Alleged Speaker: Samit Hirawat	"On December 9, 2019, Defendant Hirawat stated during an investor webcast to discuss highlights from the American Society of Hematology conference, 'as we had communicated right at the beginning of the year for liso-cel submission, we are on track for submitting liso-cel by the end of this year. And we still have a few more days to go in this month. We are on track for that.'"	• Statement not adequately alleged to be false or misleading • Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable statement of opinion under *Omnicare* • No scienter
3	¶ 237	12/18/19	Source: Press Release Alleged Speaker: BMS	"Bristol-Myers Squibb Company (NYSE: BMY) today announced the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for lisocabtagene maraleucel (liso-cel), its autologous anti-CD19 chimeric antigen receptor (CAR) T-cell immunotherapy comprising individually formulated CD8+ and CD4+ CAR T cells for the treatment of adult patients with	• Statement not adequately alleged to be false or misleading • No scienter

[1] All emphases are as they appear in the second amended complaint. ECF No. 115. Given the Court's previous dismissal with prejudice of plaintiffs' claims relating to statements in the February 22, 2019 joint proxy statement / prospectus, this chart does not include the statements in that document that plaintiffs allege to be false or misleading.

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
				relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after at least two prior therapies. The submission is based on the safety and efficacy results from the TRANSCEND NHL 001 trial, evaluating liso-cel in 269 patients with relapsed/refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL)."	
4	¶ 239	2/6/20	Source: Earnings Call Alleged Speaker: Giovanni Caforio	"On February 6, 2020 earnings call, Defendant Caforio stated that 'we continue to advance our regulatory filings for liso-cel, ide-cel and CC486."	• Statement not adequately alleged to be false or misleading • No scienter
5	¶ 242	5/6/20	Source: Press Release Alleged Speaker: BMS	"**The company will work closely with the FDA to support the continued review of the BLA for liso-cel and is committed to bringing this therapy to patients.** ******* **The company is committed to working with FDA to progress both applications and achieve the remaining regulatory milestones required by the CVR.**"	• Statements not adequately alleged to be false or misleading • Forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
6	¶ 245	5/7/20	Source: Form 10-Q Alleged Speakers: BMS Giovanni Caforio	**"Announced that the FDA has extended the PDUFA date by three months for the BLA for lisocabtagene maraleucel (liso-cel), a CD19-directed CAR T cell therapy for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date set by the FDA is November 16, 2020. . . .** **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).** We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020**. . . . **It is possible that COVID-19 could impact FDA operations such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVR. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value."	• Statements not adequately alleged to be false or misleading • Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
7	¶ 247	5/7/20	Source: Earnings Call Alleged Speaker: Samit Hirawat	"**FDA has decided that the information they have received constitute a major amendment, and that's why the PDUFA date has been extended by 3 months to 16th of November now.** ***And we are obviously committed to ensuring this medicine is available to patients as soon as possible, and we continue to meet our CVR milestones.*** Obviously we're not going to comment on the specifics of our regulatory discussions, but let me just remind that we remain very confident about the data for liso-cel for these patients with large B-cell lymphoma as it is an unmet medical need, and ***we are truly looking forward to get approval of this therapy towards the end of the year.*** Thank you. . . . **It is very normal for the FDA to, as they review the file, to ask questions.** ***Certainly, we are looking towards the approval date now to end November. . . .*** ***We remain confident and we are looking forward to bringing this treatment to patients as soon as possible towards the end of this year.***"	• Statements not adequately alleged to be false or misleading • Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter
8	¶ 249	5/19/20	Source: Presentation at UBS Virtual Global Healthcare Conference Alleged Speaker: Samit Hirawat	"On May 19, 2020, during a presentation at the UBS Virtual Global Healthcare Conference, Defendant Hirawat stated that '***we look towards hopefully approval of liso-cel towards the end of this year and we continue to go forward***.'"	• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable expression of optimism or statement of opinion under *Omnicare* • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
9	¶¶ 251-52	6/25/20	Source: Presentation at BMS Investor Day Series Alleged Speakers: Giovanni Caforio Samit Hirawat	"Liso-cel has a best-in-class CD19 targeting profile with the high affinity and differentiated safety. **We look forward to bring this call [sic] to patients soon because we have a PDUFA date of November 16 this year**. . . . **So what we learned, as we said on the call, around the** [ide-cel] **refusal to file, there were a lot many more questions around the data required in the filing from a CMC perspective. . . . For liso-cel, there are specific questions that were asked that required for us to provide more data that were considered to be large enough that the agency needed to do the scientific review of it and extended the time line through a major amendment**. . . ." "Defendant Caforio then reiterated that they felt confident about achieving approval in time for the CVR Milestone, stating that '**we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR** as well as the rest of the portfolio."	• Statements not adequately alleged to be false or misleading • Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
10	¶ 254	8/6/20	Source: Form 10-Q Alleged Speakers: BMS Giovanni Caforio	"Announced that **the FDA has extended the action date by three months for the liso-cel BLA for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date is November 16, 2020**. . . . **It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).** We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). **These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020**. . . . **It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.** Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value."	• Statements not adequately alleged to be false or misleading • Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • No scienter
11	¶ 256	8/6/20	Source Earnings Call Alleged Speaker: Giovanni Caforio.	"On an August 6, 2020 earnings call, Defendant Caforio stated that 'in the very near term, **we are looking forward to the U.S. PDUFA dates for CC-486 in September and Liso-cel in November**. And of course beyond our new launches, we have a pipeline full of promise.'"	• Statement not adequately alleged to be false or misleading • Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable expression of optimism or statement of opinion under *Omnicare* • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
12	¶ 257	9/8/20	Source: Citibank 15th Annual BioPharma Conference Presentation Alleged Speaker: Samit Hirawat	"And certainly with the evolution of the COVID-19, as well as the challenges it has posed, both for us and for the FDA, it does pose a risk because the FDA staff, like many of us, are operating under those significant constraints on travel because of COVID. Now with that said, while we typically don't provide any details on regulatory discussions, what I can say today is the FDA has informed us that they will require inspection of both our facilities in Washington State as well as the manufacturing organization for the vector, which is located in Texas. These inspections have not yet taken place. We are working very closely with the FDA to keep this application on track. **And as you know, the PDUFA date is in November, we still have some time to go. But at the same time, we are aware that some of the people -- same people who are at the FDA who will be working or working right now on liso-cel, will also be pulled into the inspection related activities that might be coming along for the COVID-related vaccines.** Now FDA is very well aware of that. They are juggling multiple things. As this is a public health crisis and they need to manage, as well as the diseases that are life-threatening, they also need to manage that. So those are all running in parallel. **I don't think we can say anything more except that the importance of this application is very, very high for us. I think it is also as important from the FDA perspective.** ***And we will continue to work closely with them, so that we can bring this product to the patients as soon as possible.***"	• Statements not adequately alleged to be false or misleading • Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter
13	¶ 259	9/15/20	Source: Panel Discussion Alleged Speaker: Samit Hirawat	"**Our PDUFA date, everybody knows, is in November, so we'll just keep on that.**"	• Statement not adequately alleged to be false or misleading • Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
14	¶ 261	9/17/20	Source: Morgan Stanley 18th Annual Global Health Care Conference Presentation Alleged Speaker: Giovanni Caforio	"**I would say the overall process with the FDA is going well. At the same time, as we mentioned last week, the FDA has informed us that they will want to inspect, they will need to inspect both of our work plans during the review process** and when we presented last week, those inspections had clearly not yet occurred. So obviously **there's the COVID and the complexity of travel during this time and I would say that is a main concern, somewhat increases the risk to the process.** I don't think there's much I can add at this point. I can tell you ***we're working very actively with the FDA to keep the review and the inspection process moving because we want to get the product to patients as soon as possible*** and we've updated the market last week and there's nothing I can add at this point."	• Statements not adequately alleged to be false or misleading • Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter
15	¶ 263	9/21/20	Source: Investor Event at European Society of Medical Oncology Alleged Speaker: Samit Hirawat	"On September 21, 2020, Defendant Hirawat participated in an investor event at the European Society of Medical Oncology, at which he stated that with respect to Liso-cel, 'we continue to work with the FDA in terms of assessing when the inspections will be. These plants have not yet been inspected. Just a reminder, we do have a breakthrough therapy designation. I remind you that we have a PDUFA date in November. As soon as the FDA will inform us, we'll certainly take that into account. But right now, we don't have a date for inspection at the time, and so they have not been inspected yet."	• Statements not adequately alleged to be false or misleading • Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter
16	¶ 265	9/24/20	Source: *Scrip Pharma Intelligence* Article Alleged Speaker: Samit Hirawat	"On September 24, 2020, *Scrip Pharma Intelligence* published an article concerning a then-recent interview with Defendant Hirawat, during which Hirawat noted that '**at this time, the liso-cel and ide-cel programs are on track to meet their approval goals.**'"	• Statement not adequately alleged to be false or misleading • Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable statement of opinion under *Omnicare* • Statements not attributable to BMS or any individual defendants

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
					• No scienter
17	¶ 267	9/30/20	Source: Committee on Oversight and Reform of the U.S. House of Representatives Alleged Speaker: Giovanni Caforio	"On September 30, 2020, Defendant Caforio made a statement before the Committee on Oversight and Reform of the U.S. House of Representatives concerning 'Bristol Myers Squibb, our acquisition of Celgene Corporation, and our focus on developing the next generation of therapies for patients' unmet medical needs,' as well as the COVID-19 pandemic. In his statement, Defendant Caforio said, '**the FDA has accepted our submissions for liso-cel and ide-cel this year, and granted priority review for both**.'"	• Statements not adequately alleged to be false or misleading • No scienter
18	¶¶ 269-70	11/5/20	Source: Form 10-Q Alleged Speakers: BMS Giovanni Caforio	"Contingent Value Right Update We have filed BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction that have not been approved by the FDA. The applications are under review by the FDA. . . . Unless the FDA approves liso-cel for the treatment of relapsed-refractory diffuse large B cell lymphoma in humans by December 31, 2020 and ide-cel for the treatment of relapsed/refractory multiple myeloma in human by March 31, 2021, no payment will be made under the CVRs and the CVRs will expire valueless. **The FDA has informed us that inspections of two manufacturing facilities are required before they can issue a decision on the liso-cel application. One of those inspections has occurred; the other has not yet been scheduled. We do not believe that the scheduling of the second site inspection is dependent on the outcome of the first site's inspection, as they are independent facilities.**" "***It is possible that the COVID-19 pandemic could delay the timing of the FDA's approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction.***	• Statements not adequately alleged to be false or misleading • Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
				We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of March 27, 2021. ***It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.*** *Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA's review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.*"	
19	¶¶ 273-74	11/5/20	Source: Earnings Call Alleged Speakers: Giovanni Caforio Samit Hirawat	"Hirawat: From liso-cel perspective, **not much to share, except for the fact that we've already communicated, we continue our dialogue with the regulatory agencies**. . . . Caforio: The only thing I would add is, just to close on what Samit mentioned **with respect to liso-cel, as always, obviously, we will update you as our discussion with the regulatory authorities progress.**" "An analyst from Morgan Stanley followed up by asking, 'So, I have two questions, please. First, could you provide more color on what you need to discuss with the FDA on liso-cel? It seemed to me that discussion should be over by this point. And a follow-up to that is, are there any issues with the recent manufacturing inspections, or do you have confidence following those manufacturing inspections?' Hirawat responded: **As we've said in the past that the conversations with the agencies are going well, and we look forward to seeing the -- hopefully, the approval at some point to be able to bring**	• Statements not adequately alleged to be false or misleading • Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Contains non-actionable expressions of optimism or statements of opinion under *Omnicare* • No scienter

Statement No.	Compl. Paragraph(s)	Date	Source and Alleged Speaker(s)	Text of Challenged Statement	Summary of Reasons Not Actionable (*See* Memorandum of Law)
				to the patients as soon as possible. We'll obviously let you know as soon as we get the decision. We are not going to comment obviously specifically about the dialogue around inspections, et cetera. We're generally very happy with the dialogue that has been happening."	
20	¶ 277	11/16/20	Source: Press Release Alleged Speaker: Samit Hirawat	**"Bristol Myers Squibb continues to work closely with the FDA to support the ongoing review of the BLA for liso-cel** said Samit Hirawat, M.D., executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. 'We are committed to bringing liso-cel to patients with relapsed or refractory large B-cell lymphoma who still have significant unmet need.' *** * *** U.S. FDA approval of liso-cel by December 31, 2020 is one of the required remaining milestones of the Contingent Value Rights issued upon the close of the Celgene acquisition in the fourth quarter of 2019. The other is U.S. FDA approval of Idecabtagene Vicleucel (ide-cel) by March 31, 2021. ***The company is committed to working with the FDA to progress both applications to achieve the remaining regulatory milestones required by the CVR.***	• Statements not adequately alleged to be false or misleading • Forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5 • Non-actionable expression of optimism or statements of opinion under *Omnicare* • No scienter

APPENDIX 2

From: Steven J. Toll <SToll@cohenmilstein.com>
Sent: Friday, May 5, 2023 2:47 PM
To: Clarke, John J., Jr.
Cc: Rosato, Steven; Masella, Jessica A.
Subject: RE: BMS CVR Securities Litigation

⚠ EXTERNAL MESSAGE

John:

You are correct – the Section 14(a) claims are included only for potential appellate purposes so you need not address them in your motion to dismiss.
You are also correct that the twelve defendants you listed are also included solely for potential appellate purposes. The answer is also "Yes" for what you said about Bancroft and Santiago re Sections 11 and 15.
Finally, the Section 20(a) claims against the outside directors for controlling person liability are also included solely with respect to the dismissed claims under Section 14(a).
Hopefully this clarifies things and answers your questions and limits what you'll address in your motion to dismiss. If any further questions, let me know.

Steve

Steven J. Toll
Managing Partner

COHENMILSTEIN

Cohen Milstein Sellers & Toll PLLC
1100 New York Ave. NW | Fifth Floor
Washington, DC 20005
phone 202.408.4600
fax 202.408.4699
website | **map**

Powerful Advocates. Meaningful Results.

From: Clarke, John J., Jr. <John.Clarke@us.dlapiper.com>
Sent: Wednesday, May 3, 2023 3:43 PM
To: Steven J. Toll <SToll@cohenmilstein.com>
Cc: Rosato, Steven <Steven.Rosato@us.dlapiper.com>; Masella, Jessica A. <jessica.masella@us.dlapiper.com>
Subject: [EXTERNAL] BMS CVR Securities Litigation

Good afternoon Steve,

I understand that in the second amended complaint plaintiffs are continuing to assert certain claims solely for purposes of appeal. However, the pleading is unclear as to certain aspects of that point.

First, in footnote 6, the second amended complaint states: "While we recognize that the Court dismissed Plaintiffs' Securities Act claims with prejudice, we are retaining them in the operating pleading for potential appellate purposes." However, the Court also dismissed plaintiffs' claims under Exchange Act § 14(a) and Rule 14d-9 with prejudice. Are we to understand that the section 14(a) claims also are included only potential appellate purposes, or do we need to address them in the motion to dismiss?

Second, the complaint continues to name the entire BMS board of directors as well as former officers Charles Bancroft and Karen Santiago as individual defendants. This includes the outside directors Peter J. Arduini, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Vicki L. Sato, Gerald L. Storch, and Karen H. Vousden. Are these twelve defendants also included in the second amended complaint solely for potential appellate purposes?

- The second amended complaint states that the only claims asserted against Mr. Bancroft and Ms. Santiago are under sections 11 and 15 of the Securities Act, so the answer to this question seems to be clearly "yes" for those two.

- On the other hand, we cannot determine plaintiffs' intention in naming the BMS directors because the allegations in Count III of the complaint, for controlling person liability under Exchange Act § 20(a), are very difficult to decipher. Is it plaintiffs' intention to assert claims under section 20(a) against the outside directors based on alleged primary violations under section 10(b) and Rule 10b-5? Or were they included solely for purposes of "controlling person" liability with respect to the now dismissed claims under Exchange Act § 14(a)

It would be helpful to come to an understanding on these questions very promptly since the answers may inform the points in our anticipated motion to dismiss. Thanks in advance for sharing plaintiffs' position.

John J. Clarke Jr.
Partner

T +1 212 335 4920
john.clarke@us.dlapiper.com

DLA Piper LLP (US)
dlapiper.com